

PLEA: Guilty.

DISPOSITION: 11-16-53. \$900 fine.

4543. B-amino-complex tablets. (F. D. C. No. 35676. S. No. 45-682 L.)

QUANTITY: 98 100-tablet btls. at Cambridge, Mass.

SHIPPED: 9-15-53 and 9-24-53, from New York, N. Y., by Unitone Corp.

LABEL IN PART: The label borne upon the above-mentioned bottles was the same as the label described in notice of judgment No. 4549.

LIBELED: 10-1-53, Dist. Mass.

CHARGE: 502 (f) (1)—the labeling of the article when shipped failed to bear adequate directions for use for the purpose for which it was intended, namely, in the treatment of deafness.

DISPOSITION: Pursuant to agreement of the parties, an order was entered on 10-29-53 directing the removal of the libel action to the Eastern District of New York. On 2-1-55, with the consent of the claimant, Unitone Corp., a decree of condemnation and destruction was entered.

4544. Polyzone device. (F. D. C. No. 36465. S. No. 69-747 L.)

QUANTITY: 1 device at Pueblo, Colo.

SHIPPED: 6-16-53, from Los Angeles, Calif., by the Polyzone Co.

ACCOMPANYING LABELING: Leaflet entitled "For Doctors Only Polyzone."

RESULTS OF INVESTIGATION: The article was assumed to consist of a device for transforming ordinary diatomic oxygen into ozone (triatomic oxygen) for administration to the human body.

LIBELED: 3-26-54, Dist. Colo.

CHARGE: 502 (a)—the accompanying labeling of the device when shipped contained false and misleading representations that ozone produced by the device was nontoxic and that the device provided, through the agency of the ozone generated by it, an adequate and effective treatment for rheumatism, sciatica, heel spurs, arthritis, male and female pelvic infections, vaginal infections, rectal inflammations, infected rectal crypts, rectal tumors, rectal fissures, colitis, hemorrhoids, fistulas, pruritus ani, spastic sphincters, inflammations of the eye, ear, nose, and throat, sinus infections, internal and external ulcerations, and all acute and chronic conditions; and, 502 (f) (1)—the labeling of the device failed to bear adequate directions for use.

DISPOSITION: 11-4-54. Default—delivered to Food and Drug Administration.

4545. Polyzone device. (Inj. No. 284.)

COMPLAINT FOR INJUNCTION FILED: 10-22-54, S. Dist. Calif., against Roy G. Collison, t/a Polyzone Co., Los Angeles, Calif.

ACCOMPANYING LABELING: A leaflet entitled "For Doctors Only Polyzone" and a booklet entitled "Polyzone Therapy Manual."

RESULTS OF INVESTIGATION: The device was designed to produce ozone by the passage of oxygen through an electrical field.

CHARGE: That the defendant was causing the introduction into interstate commerce of the *Polyzone device*, which was misbranded under 502 (a) by reason of false and misleading representations, namely:

(1) That the ozone produced by the device was beneficial and useful for all acute and chronic conditions, arthritis, catarrhal deafness, fistulas,

fungus in the ear, fungi infections, generalized itching, heel spurs, hemorrhoids, indigestion, mixed infections, otitis media, painful tooth sockets following dental surgery, pneumonia, poison ivy, poison oak, pruritus ani, pruritus vulvae, rectal fissures, rectal tumors, rheumatism, sciatica, sore throat, spastic sphincters, stomach ulcers, trench mouth, tuberculosis, deep burrowing ulcers, internal and external ulcerations, urticaria, uterine fibroids, wounds; for disorders, infections, and inflammations of the bladder, cervix, colon, ear, eustachian tubes, eyes, gallbladder, gums, intestines, liver, male and female pelvis, mouth, nerves, nose, pharynx, prostate, rectum, rectal crypts, sinuses, skin, system generally, throat, tonsils, urethra, vagina, and vulva; and for inclusion in a test for tubal patency; whereas such ozone or any other ozone was not beneficial or useful for such conditions and purposes, or for any therapeutic or diagnostic purpose;

(2) That the ozone produced by the device was nontoxic, whereas it was capable of producing toxicity when administered to the human body;

(3) That the ozone produced by the device was nonirritating to normal body tissues, whereas it was capable of causing irritation to body tissues which were normal or abnormal; and,

(4) That the ozone produced by the device was suitable for use in the treatment of sinusitis, rhinitis, otitis media, running ears, sore throat, trench mouth, tonsillitis, gum infection, painful tooth sockets, poison oak, ulcers, wounds, cryptitis, colitis, pneumonia, urethral and bladder irritations, prostate trouble, and in a test for tubal patency, whereas the labeling failed to reveal the fact, which was material in the light of such representations, that ozone was contraindicated for such conditions and purposes.

The device was alleged also to be misbranded under 502 (f) (1) in that its labeling failed to bear adequate directions for use.

DISPOSITION: 10-22-54. The defendant having consented, the court entered a decree permanently enjoining the defendant against the introduction into interstate commerce of the *Polyzone device* or any other ozone generating device when misbranded as alleged in the complaint.

DRUGS ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

4546. *Mephnesin tablets and phenobarbital tablets.* (F. D. C. No. 36838. S. Nos. 40-073 L, 40-075 L.)

QUANTITY: 4 1,000-tablet btls. of *mephnesin tablets* and 24 1,000-tablet btls. of *phenobarbital tablets* at Las Vegas, Nev.

SHIPPED: 1-2-54 and 2-17-54, from Van Nuys, Calif., by W. L. Palmer.

LABEL IN PART: (Btl.) "Tablets 3-D Brand Mephnesin Antispasmodic Muscular Relaxant Each Tablet Contains 0.5 Gram" and "Tablets Phenobarbital U. S. P. 1½ Grain (0.097 G. M. S.)."

RESULTS OF INVESTIGATION: Analyses showed that the *mephnesin tablets* contained 77.8 percent of the labeled amount of mephnesin; that the *phenobarbital tablets* contained 82.3 percent of the labeled amount of phenobarbital; and that the disintegration time of the *phenobarbital tablets* exceeded the United States Pharmacopeia maximum allowable time by 38 percent.

LIBELED: 6-18-54, Dist. Nev.

CHARGE: *Mephnesin tablets.* 501 (c)—the strength of the tablets when shipped differed from that which they purported and were represented to possess, namely, 0.5 gram of mephnesin per tablet; and, 502 (a)—the label statement "Mephnesin * * * Each Tablet Contains 0.5 Gram" was false and misleading.